COMPARISON OF MEASURED MAXILLO-PHARYNGEAL ANGLE ON LATERAL CERVICAL RADIOGRAPH & MODIFIED MALLAMPATI CLASSIFICATION IN PREDICTING DIFFICULT LARYNGOSCOPY

BY
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Background: Difficult airway management starts with evaluation of the airway to determine the likelihood of this clinical problem. Available techniques have poor to moderate sensitivity and reliability for the task. A new technique of evaluation based on maxillo-pharyngeal angle as measured on lateral cervical radiograph was described.

Objectives: This study aimed at comparing the measured maxillo-pharyngeal angle technique vs modified Mallampati classification in predicting difficult laryngoscopy by determining their diagnostic values. The study also aim at evaluating other radiographic parameters including the mandibulohyoid distance, atlanto-occipital gap, C1-C2 gap, anterior mandibular depth, posterior mandibular depth and effective mandibular length in their relationship with difficult laryngoscopy

Methodology: This was a prospective blinded comparative study with 106 patients fulfilling selection criteria recruited. Each participant was included in both groups of study with their modified Mallampati score assessed during preoperative assessment. A lateral cervical radiograph was subsequently obtained with head in neutral position and maxillo-pharyngeal angle recorded. Laryngeal view was assessed using the Cormack-Lehane grading system after induction of anaesthesia. Results of 93 participants were included and analysed. Diagnostic values of each technique were determined.

Results: The maxillo-pharyngeal angle technique was noted to be superior to modified Mallampati classification in predicting difficult laryngoscopy as evident by higher diagnostic values, most notably higher sensitivity, higher positive likelihood ratio, higher accuracy, higher diagnostic odd ratio and higher area under the ROC curve. There was no association between difficult laryngoscopy and other radiographic parameters.

Conclusion: The maxillo-pharyngeal angle technique was a superior technique in predicting difficult laryngoscopy as compared to modified Mallampati classification system.

Professor Dr Shamsul Kamalrujan Hassan (Supervisor)

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LIST OF ABBREVIATIONS

AO	Atlanto-occipital
ASA	American Society of Anaesthesiologist
AUR	Area Under the Curve
BMI	Body Mass Index
C1	First Cervical Vertebra
C2	Second Cervical Vertebra
CI	Confidence Interval
CICV	Can’t Intubate, Can’t Ventilate
CL	Cormack-Lehane gading system
CT	Computed Tomography
DAS	Difficult Airway Society
FiO2	Fractional Inspired Oxygen
FNR	False Negative Rate
FPR	False Positive Rate
HUSM	Hospital Universiti Sains Malaysia
JEPeM	Research Ethics Committee (Human) - Jawatankuasa Etika Penyelidikan (Manusia)
LMA	Laryngeal Mask Airway
LR+	Positive Likelihood Ratio
LR-	Negative Likelihood Ratio

MAC	Minimum Alveolar Concentration
MMT	Modified Mallampati Classification
MP	Maxillo-pharyngeal
MRI	Magnetic Resonance Imaging
NPV	Negative Predictive Value
OT	Operating Theatre
OR	Odd Ratio
PACS	Picture archiving and communicating system
ROC	Receiver Operating Characteristic
Se	Sensitivity
SD	Standard Deviation
SGA	Supraglottic airway
Sp	Specificity
SPSS	Statistical Package for the Social Science
PPV	Positive Predictive Value
TMD	Thyromental Distance

ABSTRAK

Perbandingan Ukuran Sudut Maxillo-Faring Pada Radiograf Sisi Leher & Klasifikasi Modified Mallampati Dalam Meramalkan Kesukaran Laringoskopi

Latar Belakang: Rawatan kesukaran saluran udara bermula dengan penilaian terhadap saluran udara untuk menentukan kemungkinan masalah klinikal ini berlaku. Teknik-teknik sedia ada didapati rendah dari segi nilai diagnostik. Satu teknik baru penilaian berdasarkan sudut maxillo-faring yang diukur pada radiograf sisi leher sisi dicadangkan.

Tujuan: Kajian ini bertujuan untuk membandingkan teknik ukuran sudut maxillo-faring berbanding klasifikasi modified-Mallampati dalam meramalkan kesukaran laringoskopi dengan menentukan nilai-nilai diagnostik berkenaan. Kajian ini juga bertujuan untuk menilai parameter-parameter radiografi yang lain termasuk jarak mandibulohyoid, jurang atlanto-ocipital, jurang C1-C2, kedalaman rahang anterior, kedalaman rahang posterior dan panjang rahang dalam hubungan mereka dengan kesukaran laringoskopi.

Kaedah: Kajian ini berbentuk perbandingan, prospektif dan “blinded dengan 106 pesakit memenuhi kriteria pemilihan diambil. Setiap peserta dimasukkan ke dalam kedua-dua kumpulan kajian dengan skor Mallampati mereka ditentukan semasa penilaian pra-pembedahan. Radiograf sisi leher kemudiannya diperolehi dengan kepala dalam kedudukan neutral dan sudut maxillo-faring direkodkan. Tahap kesukaran laringoskopi dinilai dengan menggunakan sistem penggredan Cormack-Lehane selepas induksi pembiusan dilakukan. Keputusan 93 peserta dimasukkan dan dianalisis. Nilai diagnostik setiap teknik ditentukan.

Hasil: Teknik sudut maxillo-faring didapati lebih berkesan berbanding klasifikasi modified-Mallampati dalam meramalkan kesukaran laringoskopi seperti yang dibuktikan oleh nilai-nilai diagnostik yang lebih tinggi, terutamanya sensitiviti yang lebih tinggi, specificiti yang lebih tinggi, positive likelihood ratio yang lebih tinggi, accuracy yang lebih tinggi dan area under the ROC curve yang lebih luas. Parameter-parameter radiografi lain didapati tidak seiring dengan risiko kesukaran larungoskopi.

Kesimpulan: Teknik sudut maxillo-faring adalah satu teknik yang unggul dalam meramalkan kesukaran laringoskopi berbanding klasifikasi modified-Mallampati.

ABSTRACT

Comparison Of Measured Maxillo-Pharyngeal Angle On Lateral Cervical Radiograph & Modified Mallampati Classification In Predicting Difficult Laryngoscopy

Background: Difficult airway management starts with evaluation of the airway to determine the likelihood of this clinical problem. Available techniques have poor to moderate sensitivity and reliability for the task. A new technique of evaluation based on maxillo-pharyngeal angle as measured on lateral cervical radiograph was described.

Objectives: This study aimed at comparing the measured maxillo-pharyngeal angle technique vs modified Mallampati classification in predicting difficult laryngoscopy by determining their diagnostic values. The study also aim at evaluating other radiographic parameters including the mandibulohyoid distance, atlanto-occipital gap, C1-C2 gap, anterior mandibular depth, posterior mandibular depth and effective mandibular length in their relationship with difficult laryngoscopy

Methodology: This was a prospective blinded comparative study with 106 patients fulfilling selection criteria recruited. Each participant was included in both groups of study with their modified Mallampati score assessed during preoperative assessment. A lateral cervical radiograph was subsequently obtained with head in neutral position and maxillo-pharyngeal angle recorded. Laryngeal view was assessed using the Cormack-Lehane grading system after induction of anaesthesia. Results of 93 participants were included and analysed. Diagnostic values of each technique were determined.

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Conclusion: The maxillo-pharyngeal angle technique was a superior technique in predicting difficult laryngoscopy as compared to modified Mallampati classification system.

CHAPTER 1: INTRODUCTION

According to the American Society of Anesthesiologists (ASA) Closed Claim Project, 30-40% of deaths are attributed to the inability to manage a difficult airway. 67% of difficult airway claims arose upon induction of anaesthesia, when the first placement of an endotracheal tube occurs. Shiga et.al. in a meta-analysis reported 5.8% overall incidence of difficult intubation in the general patient population and 15.8% in the obese patient. These figures proved that difficult airway continued to be a major cause of morbidity and mortality during the perioperative period.

The maintenance of airway following the initiation of general anaesthesia has always been a great concern and is the primary responsibility of anaesthesiologist. Unanticipated difficult intubation is anaesthesiologists' nightmare and when associated with "Can't intubate, can't ventilate (CICV)" situation in anaesthesized patients, it may result in catastrophic morbidity and mortality. The first step in the ASA difficult airway algorithm is the assessment of the likelihood of this clinical problem. A difficult airway is associated with various anatomical or structural variation and other individual patient factors. Identification of these factors is vital to prevent poor outcome associated with difficult airway. It has long been accepted that the thorough airway assessment prior to induction of anaesthesia is undeniably a vital means of anaesthetic planning in order to achieve a safe endotracheal intubation.

Various airway assessment modalities have been employed for this purpose. *Mallampati et al.* developed a grading system that assesses the height of the mouth, the distance from the tongue base to the roof of the mouth, and therefore the amount of space within the oral cavity available for laryngoscopy. The original three-class system was later modified by *Samsoon* and *Young* to four classes. The modified Mallampati classification has been widely studied over the past few decades and was found to have relatively high specificity but low sensitivity and a high number of false positive results. Despite that, it has become the most utilised test for predicting difficult laryngoscopy till date. Unanticipated difficult airway continues to become a major problem regardless proper airway assessment performed. Other predictor tests, in which many are simple bedside physical examination such as measurement of thyromental distance (TMD), sternomental distance, mouth opening & interincisor gap, subluxation of mandible, chin protrusion, atlanto-occipital extension, upper-lip-bite test and combination tests like combined Mallampati-TMD score and Wilson Risk Score, all have limited reliability due to poor sensitivity. The validity of these tests is very much dependent on the skill of the assessor/observer, and thence, great inter-assessor variability.

A good predictor test for difficult airway should ideally comes with high sensitivity and specificity so that false positive and false negative values are low. The result of the predictor test should be objective and reproducible to reduce inter-assessor variability. Furthermore, the effectiveness of the test is best defined independently from other tests.

Recent development has seen the birth of an objective predictor test that is free from inter-observer subjective variation. The maxillo-pharyngeal angle, as measured on a lateral cervical radiograph, was proposed as a simple, reproducible, and non-invasive radiological method to predict difficult laryngoscopy preoperatively.

Delegue et.al. first coined the term “maxillo-pharyngeal angle” in 1980. In their study on tracheal intubation of children suffering from congenital craniofacial anomalies, the authors described the association between this radiographic anatomical angle and difficult intubation. Subsequently, *Hatch et.al.* quoted that if maxillo-pharyngeal angle, as measured on the lateral cervical radiograph, is less than 90° with other normal craniofacial parameters, could result in difficult laryngoscopy. *Gupta K et.al.* performed the first study to evaluate maxillo-pharyngeal angle in predicting difficult laryngoscopy. The author found correlation between degrees of this angle and the levels of difficult laryngoscopy and with other predictive parameters and subsequently composed a classification comparable to other system that classify levels of difficult laryngoscopy including the modified Mallampati classification and Cormack-Lehane grading system.

This study aimed at validating the effectiveness of the maxillo-pharyngeal angle technique in predicting difficult laryngoscopy by providing impartial statistical values not done before by any researcher.

CHAPTER 2: LITERATURE REVIEW

2.1 THE DIFFICULT AIRWAY

The definitions of difficult airway vary from literature to literature. This study employs the one adopted by the ASA taskforce, which published a report on Difficult Airway Management in 2003. The taskforce defined a difficult airway as the clinical situation in which a conventionally trained anesthesiologist experiences difficulty with mask ventilation of the upper airway, difficulty with tracheal intubation, or both. The Task Force further noted that the difficult airway represented a complex interaction between patient factors, the clinical setting, and the skills and preferences of the practitioner. The subsets of difficult airway, their definitions and incidences are described below.

Facemask or supraglottic airway (SGA) ventilation is defined as difficult if it is not possible for the anesthesiologist to provide adequate ventilation because of one or more of the following problems: inadequate mask or SGA seal, excessive gas leak, or excessive resistance to the ingress or egress of gas. Signs of inadequate ventilation include (but are not limited to) absent or inadequate chest movement, absent or inadequate breath sounds, auscultatory signs of severe obstruction, cyanosis, gastric air entry or dilatation, decreasing or inadequate oxygen saturation (SpO_2), absent or inadequate exhaled carbon dioxide, absent or inadequate spirometric measures of exhaled gas flow, and hemodynamic changes associated with hypoxemia or hypercarbia (e.g., hypertension, tachycardia, arrhythmia). The placement of a SGA can also be difficult and this is defined as SGA placement requires multiple attempts, in the presence or absence of tracheal pathology. The incidence of difficult mask ventilation was found to be between 0.07% to 15%. One study that addressed specifically on difficult mass ventilation has found an incidence of 5% and identified 5 factors independently associated with difficult mask ventilation. These include age > 55 years, body mass index > 26kg/m^2, presence of beard, absence of teeth, and history of snoring. Another author added the presence of a large hypopharyngeal tongue as a criterion for this clinical problem. *Ovassapian* and *Glassenberg* also reported that lingual tonsil hyperplasia as a contributing factor to difficult mask ventilation.

The ASA taskforce defined difficult laryngoscopy as the inability to visualize any portion of the vocal cords after multiple attempts at conventional laryngoscopy. Laryngeal view assessment upon laryngoscopy has been classified and evolved over the last 3 decades. *Cormack* and *Lehane* divide laryngeal view into 4 grades (Figure 1.1). Although this classification is based on their study of obstetric patients in 1984, it is reproducible and applies to all types of patients. The entire glottis is visible in a grade 1 view, while in a grade 2 view only the posterior portion of the glottis can be seen; in a grade 3 view only the epiglottis can be seen, and in a grade 4 view not even the epiglottis can be seen. The authors classified a grade 3 or 4 view as difficult, and this classification has been widely accepted. The ASA task force definition incorporates both grade 3 and grade 4 views as difficult.

Yentis and *Lee* modified the Cormack-Lehane grading system by dividing the grade 2 view into 2 subclasses: Grade 2a when part of the vocal cords can be seen, while in grade 2b view only the arytenoids can be observed. Cook further expanded the original Cormack-Lehane classification into a categorical system. Grade 1 and 2a views are redefined as ‘easy’, grade 2b and 3a (epiglottis can be seen and lifted) as ‘restricted’, and grade 3b (epiglottis cannot be lifted) and grade 4 as ‘difficult’.

Although literature has reported inconsistency of the original Cormack-Lehane classification, it is still a sufficiently good system for laryngeal view assessment and as a simple gold-standard covariate for the purpose of comparative study. This classification is most widely used in clinical settings and would allow analysis of data and cross-study comparisons. Thence, it is utilsed in this research. The incidence of difficult laryngoscopy has been reported to be 1 – 5% in various studies. Several factors have been found to affect laryngeal view during a conventional laryngoscopy. These include normal variants of airway anatomy (e.g. short neck, anterior larynx, large tongue, high-arch palate, receding chin, obesity), pathological conditions (e.g. laryngeal or pharyngeal mass), and position of the patient during laryngoscopy.

Difficult tracheal intubation has been defined as the need for multiple attempts at intubation, in the presence or absence of tracheal pathology, and which may be due to difficult laryngoscopy or other factors. Others defined difficult intubation as requiring the use of gum elastic bougie or special equipment. Since the definitions of difficult intubation are more varied, difficult laryngoscopy rather than difficult intubation is used as end-point in this study. In a meta-analysis of 35 studies, the overall incidence of difficult intubation was 5.8% for the overall patient population, 6.2% for normal patients excluding obstetric and obese patients, 3.1% for obstetric patients, and 15.8% for obese patients. The factors that affect intubation are generally similar to those affect laryngeal view at laryngoscopy. However, intubation may still be difficult despite the presence of a grade 1 or grade 2 views at laryngoscopy. This occurs when anatomical factors such as subglottic stenosis, tumours compressing the trachea, an anterior larynx, and vocal cord pathology such as the presence of polyps or tumour that make the passage of an endotracheal tube difficult.

2.2 PREDICTING DIFFICULT AIRWAY

Management of airway progresses over a 3-phase process: airway evaluation, actual management of the airway (i.e. mask-ventilation, laryngoscopy & tracheal intubation), and extubation of the airway. The first phase, airway evaluation forms the basis for the development of primary and secondary strategies in phase two of airway management. It aims at predicting potential difficulty in mask ventilation, laryngoscopy and tracheal intubation. This should involve a thorough history and physical examination that also involves a series of specific predictive tests.

The ASA task force recommends an airway history be conducted before the initiation of anaesthetic care. A direct medical history or review of medical records may reveal certain disease states, specific patients characteristics or congenital disorders that may complicate airway management. These may include acquired conditions such as morbid obesity, acromegaly, infections involving the airway (Ludwig's angina), rheumatoid arthritis, obstructive sleep apnoea, ankylosing spondylitis, subglottic stenosis, lingual thyroid, tonsillar hypertrophy, tumours involving the airway, and trauma (airway, cervical spine) and congenital disorders such as Pierrre–Robin syndrome, Down's syndrome, Treacher–Collins syndrome, Goldenhar's syndrome, Klippel-Feil syndrome, mucopolysaccharidoses, achondroplasia, and micrognathia. Apart from these conditions, a past history of difficult airway or history of complication related to management of airway such as broken tooth or severe sore throat postoperatively, may be helpful in guiding airway management.

The ASA taskforce recommends assessment of several airway features that may be associated with difficult airway. These include the length of upper incisors (relatively long), relation of maxillary and mandibular incisors during normal jaw closure and during voluntary protrusion (prominent overbite and maxillary incisors anterior to mandibular incisors), inter-incisor distance (less than 3 cm), visibility of uvula (not visible when tongue is protruded), shape of palate (high arch), compliance of mandibular space (stiff, indurated, occupied by mass, or non-resilient), thyromental distance (less than three ordinary finger breadths), length of neck (short), thickness of neck (thick), and range of motion of head and neck (patient cannot touch tip of chin to chest or cannot extend neck). The presence of acquired problems such as head/neck burns, abscesses, radiotherapy injury, restrictive scars, poor dentition, and use of orthopaedic/neurosurgical/orthodontic equipment (e.g. halo traction, stereotactic locator, dental wiring) should also be sought.

Many of the above features can be assessed via bedside tests developed specifically to address and grade airway difficulty. Some of the most commonly used predictive tests include the modified Mallampati classification, measurement of thyromental distance, sternomental distance, interincisors gap and Wilsons' risk score. *Mallampati et.al* first correlates a large tongue to difficulty in exposing the larynx and thus difficult laryngoscopy. Since a large tongue also obscure the uvula, tonsillar pillars and the soft palate, the authors developed a system that correlates the visibility of these structures to laryngeal view at laryngoscopy. In the original paper published in 1985, the Mallampati classification consists of 3 classes, based on assessment with the patient sitting up and maximally protruding the tongue without phonation: Class I described full visualization of all three structures, Class II allowed visualization of only the faucial pillars and soft palate, and in Class III patients only the soft palate was visible. *Samsoon* and *Young* added a fourth class where even the soft palate is not visualized (Figure 1.2). Class III and IV are generally accepted to predicts difficult intubation. *Savva* first described a sternomental distance of less than 12.5cm to be associated with difficult intubation. *Khan et.al.* proposed the inability to bite upper lip with lower incisors (Class III in their classification) as a risk of difficult intubation.

Various combination tests, which classify airway difficulty based on a sum of risk score has been studied. *Wilson et.al.* found five factors associated with difficult intubation: weight, upper cervical spine movement, jaw movement, receding mandible and protruding upper teeth. Each factor is subjectively given a score of 0-2 upon assessment. A total score of 2 or more predicts 75% of difficult intubation. *Rocke et.al.* demonstrated Mallampati Class III or IV, short neck, obesity, receding mandible, protruding, missing, or single maxillary incisor as predictors of difficult intubation. *Rose* and *Cohen* showed a reduced mouth opening, reduced thyromental distance, and reduced visualization of hypopharynx to be associated with difficult intubation. Similar multivariate scoring systems were used by *Nath* and *Sekar*, *Arne et.al.*, *Naguib et.al.*, *Karkouti et.al.*, and *Ezri et.al.*

2.3 LIMITATIONS OF AVAILABLE PREDICTIVE TESTS

Despite a variety of tests available for the evaluation of airway, there is no single factor/predictive test or group of factors/tests has been shown to have high specificity, sensitivity, or positive predictive value for predicting difficult laryngoscopy or intubation. *Butler* and *Dhara* evaluated Mallampati classification and thyromental distance in predicting difficult intubation and found both tests to be low in sensitivity, specificity and positive predictive value. Similarly, *Tse et.al.* studied Mallampati classification, thyromental distance and head extension and found none of the factors showed high sensitivity nor predictive value. A meta-analysis of 35 studies by *Shiga et.al.* reported a poor-to-moderate pooled sensitivity of most predictor tests available, ranging from 20% (thyromental distance) to 62%(sternomental distance). The Mallampati classification has a sensitivity of 41-57%. Combining a group of factors may yield higher predictive value but reduces sensitivity. *Oates et.al.* compared Mallampati classification and the Wilson risk score and found both have poor sensitivity.

The Mallampati classification and most other tests have been criticized for their significant inter-observer variability. *Karkouti et.al.* conducted a prospective study to determine inter-observer reliability of ten preoperative airway assessment tests used for predicting difficult tracheal intubation and found that many of the preoperative airway tests have only moderate inter-observer reliability. Only mouth opening and chin protrusion was found to have good inter-observer reliability. Mallampati classification had poor reliability. The poor inter-observer reliability of these predictive tests can be explained by the dependence of the test on assessor's skill and subjective evaluation, which can significantly varies among assessors.

2.4 ROLE OF IMAGING TECHNIQUES IN AIRWAY EVALUATION

As difficult airway is related to structural abnormality or variation of the head and neck, imaging techniques may reveal findings not detected on physical examination. *White* and *Kander* retrospectively reviewed lateral cervical radiographs of 13 patients with difficult intubation and found that the posterior depth of mandible (i.e. the distance between the body alveolus immediately behind the third molar tooth and the lower border of the mandible) and the distance between the C1 vertebra and occiput (atlanto-occiput gap) as important measures in determining the ease or difficulty of laryngoscopy. *Chou* and *Wu* demonstrated an increase in the mandibulo-hyoid distance and shorter effective mandibular length as measured on lateral cervical radiograph resulted in difficult laryngoscopy. Other parameters on a lateral skeletal film that can be used to assess airway difficulty include the C1-C2 gap and anterior mandibular depth. *Samra et.al.*, however, in their prospective studies on 21 parameters of radiological imaging techniques, did not show significant difference in X-ray or MRI studies between difficult intubation patients and controls.

Other imaging modalities have been used to evaluate the airway with the aim of diagnosing specific abnormalities that affect airway. Ultrasound, CT and MRI are known to be useful in detecting pharyngeal or laryngeal pathology such as tumours, abscesses and epiglottis. *Rudman et.al.* and *Berg et.al.* separately determined airway fluoroscopy as a reliable dynamic technique to diagnose laryngomalacia, tracheomalacia, airway stenosis, and airway masses in children. Ultrasound has been employed to quantify the anterior neck soft tissue. *Ezri et.al.* found that the sonographic measurement of pretracheal soft tissue at the level of the vocal cords a good predictor of difficult laryngoscopy in Middle Eastern obese patients. However, *Komatasu et.al.* could not replicate these findings in the American obese patients. *Siegel et.al.* validated the use of upper airway ultrasonography to visualize approximation of the tongue base posteriorly and inferiorly towards the hypopharynx to cause airway obstruction. *Caballero et.al.* used CT to evaluate the airway and demonstrated a relationship between difficult airway and the presence of abundant neck soft tissue in the pharynx, retropharynx and suprascapular region. *Abe et.al.* revealed similar findings with MRI.

2.5 THE MAXILLO-PHARYNGEAL ANGLE ON LATERAL CERVICAL RADIOGRAPH AND IT'S ROLE IN AIRWAY EVALUATION

Delegue et.al. first coined the term "maxillo-pharyngeal angle" in 1980. In their study, the authors described the association between this angle and difficult intubation. *D.J. Hatch*, in his article on airway management in cleft lip and palate surgery, quoted that if maxillo-pharyngeal angle, as measured on the lateral cervical radiograph, is less than 90° with other normal craniofacial parameters, could result in difficult laryngoscopy. *Gupta K et.al.* performed the first study to evaluate maxillo-pharyngeal angle for better understanding of the pathophysiology of difficult laryngoscopy. The authors described the angle as an upper airway anatomical balance, which if deranged, would results in airway difficulty upon laryngoscopy. They were prompted to conduct the study after encountering a case of failed intubation, which retrospectively found to have a maxillo-pharyngeal angle of less than 90°. The results of the study indicated that when the maxillo-pharyngeal angle was between 110° and 100°, direct laryngoscopy could be performed easily and when the angle was less than 90°, it was difficult, if not impossible, to visualize the larynx at direct laryngoscopy. The authors subsequently developed a categorical system comparable to Mallampati classification to correlate ease of laryngoscopy defined by the Cormack-Lehane grades to the maxillo-pharyngeal angles (Figure 1.3 & Figure 1.4).

According to *Gupta*, the measurement of maxillo-pharyngeal angle on the lateral cervical radiograph is a simple, reproducible and non-invasive radiological technique to predict difficult laryngoscopy. *Adnet et.al.* defined the Maxillo-pharyngeal angle as the angle between the Maxillary Axis (the line parallel to the hard palate) & the Pharyngeal Axis (the line passing through the anterior portion of the first and second cervical vertebrae) and this can be measured on a lateral cervical radiograph taken in erect posture with the head of the patient in neutral position. *Schriger et.al.*, described neutral position of the head, neck and torso as the normal anatomical position that one assumes when standing looking straight ahead or the most naturally correct anatomical position of the cervical spine with the patient's gaze perpendicular to the horizontal plane of a backboard. This can be determined by aligning patient's tragus and midaxillary line and by instructing the patient to look at a fixed target located at eye level.

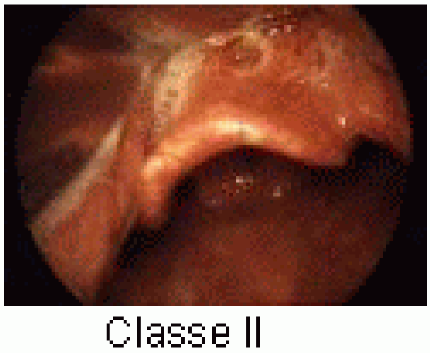
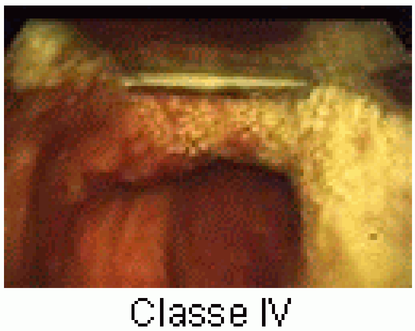
The Cormack-Lehane Classification	
Class I = Visualization of the entire laryngeal aperture	
Class II = Visualization of parts of the laryngeal aperture or the arytenoids	
Class III = No part of the glottis can be seen except the epiglottis	
Class IV = Not even the epiglottis can be seen	

Figure 1.1: The Cormack-Lehane Classification

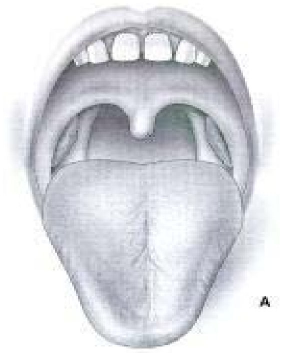
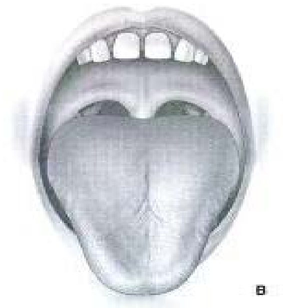
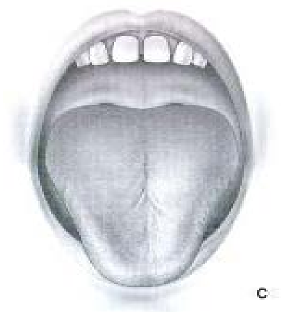
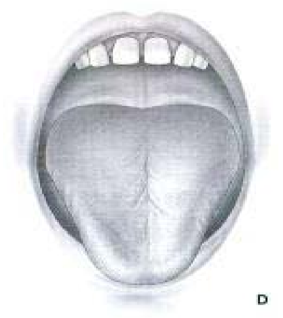
Modified Mallampati Classification	
Class I = soft palate, fauces, uvula and pillars seen	
Class II = soft palate, fauces, and uvula seen	
Class III = soft palate and base of uvula seen	
Class IV = soft palate not visible	

Figure 1.2: The Modified Mallampati Classification

Maxillo-pharyngeal (M-P) Angle:

Predicted Outcome	Proposed Classification	M-P Angle
Easy	Class I	>110°
	Class II	110-90°
Difficult	Class II	<90°
	Class IV	<85°

Figure 1.3: The proposed classification of maxillo-pharyngeal angle technique, its association with difficult laryngoscopy

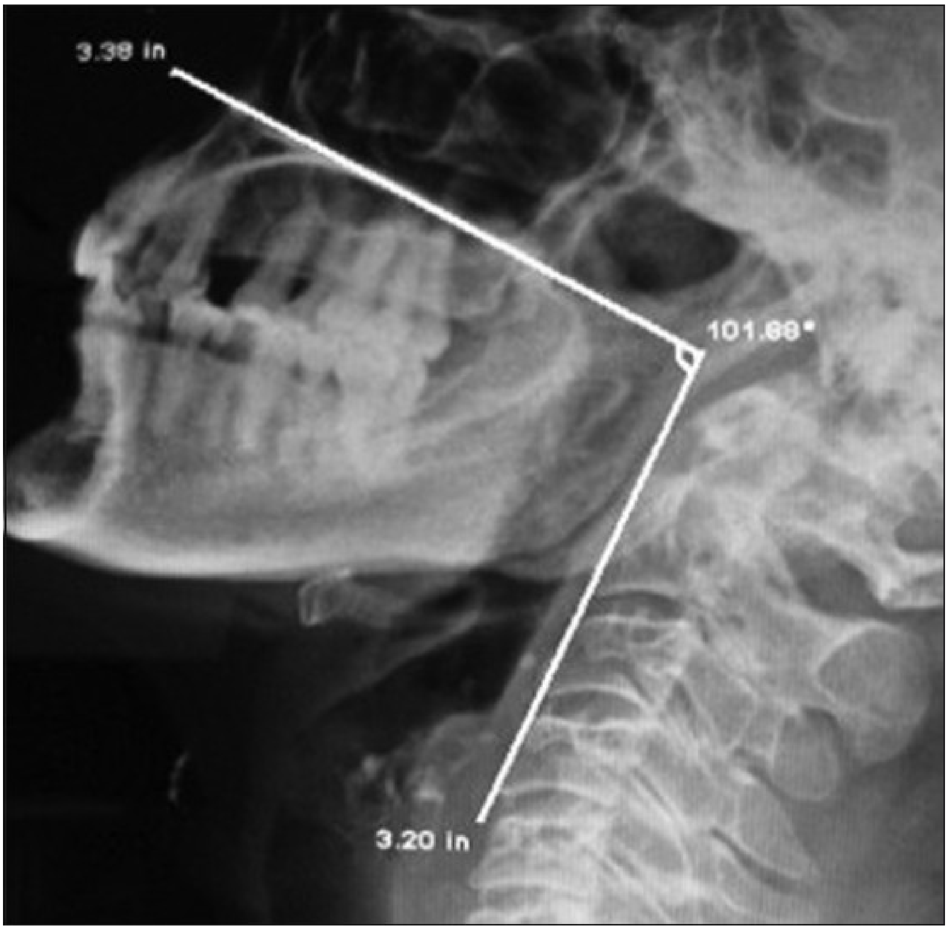


Figure 1.4: An example of lateral cervical radiograph with measurement of the maxillo-pharyngeal angle formed by the maxillary axis and pharyngeal axis

CHAPTER 3: OBJECTIVES OF STUDY

3.1 PRIMARY OBJECTIVES

The primary objective of this study is to evaluate and to compare the measured Maxillo-pharyngeal angle technique and the modified Mallampati classification in predicting difficult laryngoscopy.

Specifically, statistical diagnostic values, including sensitivity, specificity, positive predictive value and negative predictive values of both techniques are established, analyzed and compared to determine if the proposed maxillo-pharyngeal angle technique is an inferior, equal or superior alternative to the commonly used modified Mallampati classification in airway evaluation to predict difficult laryngoscopy.

3.2 SECONDARY OBJECTIVES

On top of the main study objective, this study also aim at the following:

3.2.1 To determine the prevalence of difficult laryngoscopy at the site of study (major operating theatre of HUSM) during the period of study. This can be calculated as:

$$\textit{6-month prevalence} = \frac{\textit{number of patients with Cormack-Lehane Classification III \& IV}}{\textit{total number of patients studied}}$$

3.2.2 To determine the association between difficult laryngoscopy and other radiographic parameters obtained from lateral cervical radiograph including:

i. *Mandibulohyoid distance*
ii. *Atlanto-occipital gap*
iii. *C1-C2 gap*
iv. *Anterior mandibular depth*
v. *Posterior mandibular depth*
vi. *Effective mandibular length*

3.3 REASEARCH HYPOTHESIS

3.3.1 The measured Maxillo-pharyngeal angle technique is more effective with higher sensitivity and specificity and lower false positive and false negative than modified Mallampati classification in predicting difficult laryngoscopy and thus a superior technique in airway evaluation.

3.3.2 There is an increased risk of difficult laryngoscopy with the following radiographic parameters:

i. *Increased mandibulo-hyoid distance*
ii. *Reduced space between C1 and occiput (AO-gap)*
iii. *Reduced space between C1 and C2 (C1-C2-gap)*
iv. *Increased posterior mandibular depth*
v. *Increased anterior mandibular depth*
vi. *Decreased effective mandibular length*

3.4 NULL HYPOTHESIS

3.4.1 The measured Maxillo-pharyngeal angle technique is inferior or not better than modified Mallampati classification in predicting difficult laryngoscopy.

3.4.2 The following radiographic parameters are not associated with an increased risk of difficult laryngoscopy or the reverse is true:

i. *Increased mandibulo-hyoid distance*
ii. *Reduced space between C1 and occiput (AO-gap)*
iii. *Reduced space between C1 and C2 (C1-C2-gap)*
iv. *Reduced posterior mandibular depth*
v. *Reduced anterior mandibular depth*
vi. *Decreased effective mandibular length*

CHAPTER 4: METHODOLOGY

4.1 STUDY DESIGN

The study design incorporates a blinded, prospective comparative nature on a diagnostic examination (the Maxillo-pharyngeal angle technique), with modified Mallampati classification as the control variable and Cormack-Lehane classification as the gold-standard predictor of difficult intubation

4.2 SITE OF STUDY

The study was conducted at the major operating theatre of Hospital Universiti Sains Malaysia.

4.3 STUDY TIME FRAME

The study was conducted over a period of 6 months beginning in February 2014. Data collection was completed at the end June 2014. The data was analyzed in the subsequent month. The report of the research was then prepared and revised numerous times.

4.4 ETHICAL APPROVAL

The study protocol was presented to the Research Ethics Committee (Human) *(JEPeM)* of Universiti Sains Malaysia. An official approval was obtained in February 2014.

4.5 REFERENCE POPULATION, SAMPLING FRAME AND SAMPLING METHOD

The reference population comprises all patients admitted to the Hospital Universiti Sains Malaysia. Patients who were to undergo surgery in the major operating theatre were included in the sampling frame.

The patient recruitment was based on simple random sampling method to ensure all patients in the sampling frame were given an equal probability for selection and to eliminate bias. Recruitment was done in the wards after referring to the lists of patients scheduled for surgery on the next day of sampling. Patients were selected randomly from the lists and then evaluated for suitability for participation based on inclusion and exclusion criteria.

Written informed consents were obtained. Recruited patients were assigned a Subject Identification Code.

4.6 SAMPLE SIZE CALCULATION

The single proportion formula was used to calculate sample size:

$$\boldsymbol{N} = \left(\frac{\boldsymbol{Z\alpha}}{\Delta}\right)^{\boldsymbol{2}} * \boldsymbol{P}(\boldsymbol{1} - \boldsymbol{P})$$

4 separate possible sample sizes were determined based on statistical parameters sensitivity and specificity of the respective predictive examinations in previous studies. As no values on sensitivity nor specificity of maxillo-pharyngeal technique was previously reported, the values of modified Mallampati classification were used as reference. These values were obtained from the meta-analysis by *Shiga et.al.*

The reference sensitivity and specificity of maxillo-pharyngeal angle techniques were then extrapolated as a 10% clinically important difference from the respective values of modified Mallampati classification:

Test	***Sensitivity***	***Specificity***
MMT Classification	***0.49***	***0.86***
MP-Angle *(10% difference)*	***0.59***	***0.96***

Based on the meta-analysis by Shiga et.al

Using

- An α-value (probability of committing type 1 error) of 0.05
- $Z\alpha$ (Standard normal variate) = 1.96
- Δ (Precision of study) = 0.1

Sample sizes (N) were determined as follow:

Test	***Sensitivity***	***Specificity***
Mallampati Classification	***N = 96***	***N = 46***
MP-Angle *(10% difference)*	***N = 93***	***N = 15***

A sample size of 96 per group was required to determine the diagnostic values of each group. In order to reduce variability of subjects in the 2 groups to allow more precise comparison with fewer subjects needed, pairing of subjects were done and thus a total of 96 patients were required for the entire study. A dropout rate of 10% was proposed resulting in a recruitment requirement of 106 patients